UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,871	04/13/2004	Robert J. Deleys	BJS-2551-141	3673

23117 7590 02/05/2008

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
BLUMEL, BENJAMIN P	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
02/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,871	DELEYS ET AL.	
	Examiner	Art Unit	
	Benjamin P. Blumel	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55,59,60 and 68-93* is/are pending in the application.

4a) Of the above claim(s) *74-76 and 90-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *55,59,60,62,68-73 and 77-89* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *4/13/04 and 8/18/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 07/920,286.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants are informed that the objections/rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's amendments.

Election/Restrictions

This application contains claims 74-76 and 90-93 drawn to an invention nonelected or species with traverse in the reply filed on February 2, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 55, 59, 60, 62, 68-73 and 77-89 are examined on the merits.

Response to Arguments

Applicant's arguments filed November 2, 2007 have been fully considered but they are not persuasive. Applicants argue that it is inconsistent for the Examiner to assert that the claims of the present application are allegedly anticipated or obvious over the cited patents while also asserting that claims which are patentable over the cited art (i.e., the claims of U.S. Patent Nos. 5,910,404; 5,922,532; 6,287,761; 6,576,417; and 6,872,520) would have made the presently claimed invention obvious. Therefore, the Examiner is requested to either withdraw the 35 U.S.C. 102/103 rejection of claims 55, 59, 60, 62, 68-73 and 77-89 over Houghton (U.S. Patent No. 5,350,671) or withdraw the obviousness-type double patenting rejections (see below). In response, applicants are reminded that each patent application is examined on its merits independently from previously filed or co-pending applications with common inventorship and/or assignment. Furthermore, the scope of the instant invention is broader as compared to that of the patented inventions cited below, since the instant invention claims amino acids

sequences from any HCV polyprotein or from specific SEQ ID NO:s. There is nothing inconsistent in the position that some claim embodiments which are not already patented are unpatentable over the prior art. Therefore, the nonstatutory obviousness-type double patenting and 35 U.S.C. 102/103 rejections are maintained for reasons of record, see responses below.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(Prior Rejection Maintained) Claims 55, 59, 60, 62, 68-73 and 77-89 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over:

claims 1-7, 12, 19-22, 27, 32, 33 and 38 of U.S. Patent No. 6,007,982;

claims 1-6, 13-15, 22, 23, 26, 39 and 40 of U.S. Patent No. 5,910,404;

claims 1-6, 13-24 and 26 of U.S. Patent No. 6,872,520 B2;

claims 1-5, 7, 12 and 21-24 of U.S. Patent No. 5,922,532;

claims 1-3, 5-7, 9-11, 13-15, 17-24, 27 and 28 of U.S. Patent No. 6,287,761 B1; and

claims 1, 3, 4, 6, 7 and 9-12 of U.S. Patent No. 6,576,417 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed invention of the instant application is drawn to an immunoassay kit which uses capsid, non-structural and core antigens of Hepatitis C virus. These antigens are represented by SEQ ID NO:s 1-20 which are fragments of SEQ ID NO:23. However, the patented inventions as claimed above, are also drawn to a kit for detecting anti-HCV antibodies via various combinations of SEQ ID NO:s 1-20 (the same amino acids sequences as in the instant invention) in immunoassay plates. Therefore, the instant invention is an obvious variant of the patented kits of '982, '404, '520, '532, '761 and '417 which renders the instant invention unpatentable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(New Rejection Necessitated by Amendments) Claims 55, 59, 60, 62, 68-73 and 77-89 are rejected under 35 U.S.C. 102(e) as anticipated by Houghton et al. (US 5,350,671).

Applicants argue that Houghton et al. are not enabled for immunodiagnostic peptides of HCV Core, NS4 or NS5 epitopes and that Houghton et al. only teach computer analysis of potential immunogenic epitopes that may be useful in HCV diagnostic methods. In addition, applicants also argue that they were the first to discover different HCV diagnostic proteins for

reactive antibody assays and that Houghton et al. do not teach which regions of HCV polyproteins are diagnostically preferred. Applicants also request that the Examiner reviews the evidence of record from applications 08/466,975 and 08/391,671.

In response, the examiner has reviewed the supplemental information from applications '975 and '671 and has determined that the peptides taught by Houghton et al. that resemble peptides of the claimed invention (i.e., VIII-XIII, etc.) perform similarly based on the data presented. For example, the inventors state in these comparison tests that the Houghton et al. peptides "react in a very similar way with the HCV positive samples tested and in comparison with peptide VIII" (see page 8 of 11/2/07 response). Furthermore, applicants state on page 14 of the same response that peptide XIII of the instant invention "did not show any advantages in an ELISA format over peptide 1720-1745", a Houghton et al. peptide. Therefore, these compared Houghton et al. peptides are enabled for being immunodiagnostic peptides. Moreover, Houghton et al. disclose in column 81, lines 55-65, the approximate amino acid regions for HCV capsid, NS4 and NS5 proteins, with more detailed regions provided on column 83, lines 34-53. Furthermore, patent applications are not required to have working examples as stated in the MPEP § 2164.02 "An example may be "working" or "prophetic."...The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation."

Lastly, Houghton et al. teach homologous amino acid sequences of the claimed invention since it is broadly drawn to protein combinations with at least 5 amino acids of any HCV polyprotein, see figure 66A&B which contain the entire sequence of an HCV polyprotein. Within this figure and the summarized amino acid domains stated below (derived from column

28, lines 67 and 68 to column 29, lines 1-68), Houghton et al. discloses the broadly claimed invention of combinations of any HCV polyprotein fragments.

With regard to claim 55, Houghton et al. teaches amino acids 1-20, 1688-1707 and 2311-2330 of a HCV polypeptide with at least 5 residues identical to SEQ ID NO: 1, 9 and 20 respectively.

With regard to claim 71-74, Houghton et al. also teach amino acids 1-92, 1688-1749 and 2263-2330 of a HCV polyprotein (see figure 66A&B) and table summarized below.

With regard to claims 77-80, Houghton et al. teach the use of HCV polypeptides which exclude amino acids 1-6 of any HCV polypeptide (see columns 28 and 29).

Therefore, the claimed invention remains anticipated by Houghton et al.

AA-AA of Houghton et al.	Claimed Amino acid positions
AA1-AA25	1-20, 7-26
AA5-AA20	8-18
AA1-AA50	13-32
AA1-AA84	37-56
AA45-AA65	49-68
AA65-AA75	61-80
AA80-AA92	73-92
AA1690-AA1720	1688-1707, 1694-1713, 1706-1725
AA1694-AA1735	1712-1731, 1718-1737
AA1720-AA1745	1724-1743, 1730-1749
AA2265-AA2280	2263-2282
AA2275-AA2294	2275-2294
AA2290-AA2310	2287-2306, 2299-2318
AA2310-AA2330	2311-2330

Summary

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Blumel whose telephone number is 571-272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin P Blumel/
Examiner
Art Unit 1648

/Bruce Campell/
Supervisory Patent Examiner
Art Unit 1648